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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/032,962 | 10/24/2001 | Matthew Heidner | 1001.1479101 | 8725 |
| 28075 | 7590 | 05/28/2004 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | THALER, MICHAEL H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/032,962 | Applicant(s) HEIDNER, MATTHEW | |
| | Examiner Michael Thaler | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7,9,10,15,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,11-14,16 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/12,4/3/02,6/1303</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 7, 9, 10, 15, 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed March 17, 2004.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, 11-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is unclear if the claimed subject matter is 1) the final product of a catheter which has a reduced profile subsequent to the thermal formation and which apparently no longer has any voids or 2) an assembly of a shaft and balloon at an intermediate stage of production prior to thermal reformation wherein the balloon waist includes a plurality of voids. Claim 11 is indefinite for similar reasons.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 11-14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sugiyama et al. (4,964,853). Claim 1, as best understood, is considered to define the final product of a balloon catheter which has a reduced profile subsequent to the thermal formation and which no longer has any voids, in view of the preamble of the claim which is "A balloon catheter" which implies the final product of a balloon catheter. Thus, Sugiyama et al. disclose elongate shaft 1, 2 and balloon 3 having a balloon waist 7. The phrase "including a plurality of voids prior to thermal reformation that cause the balloon waist to have a reduced profile subsequent to thermal reformation" is considered to be a product by process limitation. The final product has no voids since the melted and flowing polymeric

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material pools into the voids as indicated on page 8, lines 11-16 of the specification. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process (MPEP 2113). In this case, the product of a balloon dilatation catheter in the product-by-process claim is certainly the same as or obvious from the Sugiyama et al. product of a balloon dilatation catheter. Alternatively, it would have been obvious that the Sugiyama et al. product of a balloon dilatation catheter meets the terms of lines 3-6 of claim 1 for the reasons set forth above. As to claim 3, Sugiyama et al. disclose a taper on waist 7 at its extreme distal end as seen in figure 1. As to claim 5, Sugiyama et al. disclose proximal waist 8 and distal waist 7. Claim 11, as best understood, is considered to define the final product of a balloon catheter which is disclosed by or obvious in view of Sugiyama et al. for the reasons set forth above.

Claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cornelius (5,649,909). Cornelius discloses the steps of providing a catheter shaft 36 (figure 3), providing an

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expandable balloon 38 having a waist (54 or 63), forming a plurality of voids in the balloon waist (The voids referred to in col. 7, lines 40-45 are "in the balloon waist" as broadly claimed in claim 19, line 4 since they are radially within the waist. These voids are also inherently formed during the manufacturing methods described in col. 7, lines 19-34 before the waists are heat shrunk or welded onto shaft 36.), thermally reforming the waist to close the voids and to reduce the profile of the waist (the heat shrinking or welding steps described in col. 7, lines 19-34) and attaching the waist to the distal end of the catheter shaft (during the heat shrinking or welding steps described above). Alternatively, it would have been obvious that voids are also formed during the methods described in col. 7, lines 19-34 since they are formed during the manufacturing method described in col. 7, lines 35-45.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht

5/27/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731